# ATHLETES FOOT- terbinafine hydrochloride cream Strategic Sourcing Services LLC

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#### Athlete's Foot Cream

**Drug Facts** 

#### **Active ingredient**

Terbinafine hydrochloride 1%

#### **Purpose**

Antifungal

#### Uses

- cures most athlete's foot (tinea pedis)
- cures most jock itch (tinea cruris) and ringworm (tinea corporis)
- relieves itching, burning, cracking and scaling which accompany these conditions

#### Warnings

#### For external use only

#### Do not use

- on nails or scalp
- in or near the mouth or the eyes
- for vaginal yeast infections

**When using this product** do not get into the eyes. If eye contact occurs, rinse thoroughly with water.

#### Stop use and ask a doctor if

- too much irritation occurs or gets worse.
- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.

**Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

#### **Directions**

- adults and children 12 years and older
  - use the tip of the cap to break the seal and open the tube
  - wash the affected skin with soap and water and dry completely before applying
  - **for athlete's foot** wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.
    - **between the toes only:** apply twice a day (morning and night) for **1 week** or as directed by a doctor.
    - on the hottom or sides of the foot: apply twice a day (morning

1 week between the toes



2 weeks on the bottom or sides of the foot

and night) for **2 weeks** or as directed by a doctor.

- **for jock itch and ringworm:** apply once a day (morning **or** night) for **1 week** or as directed by a doctor.
- wash hands after each use
- children under 12 years: ask a doctor



#### Other information

- do not use if seal on tube is broken or is not visible
- store at controlled room temperature 20°-25°C (68°-77°F)
- see carton or tube crimp for lot number and expiration date

#### **Inactive ingredients**

benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan monostearate, stearyl alcohol.

Distributed by McKesson One Post Street San Francisco, CA 94104

#### PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

sunmark<sup>®</sup>
athlete's foot cream
terbinafine hydrochloride cream 1%
antifungal cream
FULL PRESCRIPTION STRENGTH
NET WT 1 oz (30 g)

COMPARE TO LAMISIL AT® **ACTIVE INGREDIENT\*** 

### **Relieves Itching & Burning** Cures Most Athlete's Foot

**FULL PRESCRIPTION STRENGTH** 

LPK-6115-0 0708-0 M115

## sun mark \* athlete's foot cream

terbinafine hydrochloride cream 1%

antifungal cream

**FULL PRESCRIPTION STRENGTH** 

NETWT1 oz (30 g)

sopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan Inactive ingredients: benzyl alcohol, cetyl alcohol, cetyl palmitate,

- do not use if sest on tube is broken or is not visible store at controlled room temperature 20°-25°C (88°-77°P) see carlon or tube crimp for lot number and expiration data
  - - Other information

Drug Facts (continued)



**W**EKE2SON





2 weeks on the bottom



- · wash hands after each use
- or as directed by a doctor.

   for jock first and ringworm: apply once a day (morning or right) for 1 week
- on the bottom or sides of the foot apply wice a day (morning and night)
   for 2 weeks or as directed by a doctor.
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   or as directed by a doctor. at least once daily.
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   for athlete's foot west well-fitting, ventilated shoes. Change shoes and socks

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Active ingredient Terbinatine hydrochlonde 1%

For external use only

Drug Facts

terbinatine hydrochloride cream 1% athlete's foot cream



#### ATHLETES FOOT

terbinafine hydrochloride cream

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-790
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Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Terbinafine Hydrochloride (UNII: 012C11ZU6G) (Terbinafine - UNII:G7RIW8S0XP)	Terbinafine Hydrochloride	1 g in 100 g

# Inactive Ingredients Ingredient Name Strength

benzyl alcohol (UNII: LKG8494WBH)

cetyl alcohol (UNII: 936JST6JCN)

cetyl palmitate (UNII: 5ZA2S6B08X)

isopropyl myristate (UNII: 0RE8K4LNJS)

polysorbate 60 (UNII: CAL22UVI4M)

water (UNII: 059QF0KO0R)

sodium hydroxide (UNII: 55X04QC32I)

sorbitan monostearate (UNII: NVZ4I0 H58 X)

stearyl alcohol (UNII: 2KR89I4H1Y)

#### **Product Characteristics**

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:49348-790-72	1 in 1 CARTON	12/12/20 12	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		

## **Marketing Information**

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA077511	07/02/2007		

## Labeler - Strategic Sourcing Services LLC (116956644)

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(49348-790)	

Revised: 11/2019 Strategic Sourcing Services LLC